REMARKS/ARGUMENTS

This is in response to the Office Action dated July 10, 2003. Claims 1-24 are pending in the application. No claims stand allowed. This action is Final.

Claims 1-24 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 1 is deemed to be indefinite because there is no requirement that the mammal receiving the administration be the one in which treatment or prevention is to be accomplished. The Examiner has suggested that the rejection can be overcome by amending claims 1, 5, 10, 15 and 20 to require that the mammal receiving the administration be the one in which the intended result is to be accomplished. By the present amendment claims 1, 5, 10, 15 and 20 have been amended in the manner suggested by the Examiner.

Reconsideration of the rejection of claims 1-24 under 35 U.S.C. §112, second paragraph, is courteously requested.

Claims 1, 2, 10, 11, 15, 16, 20 and 21 are again rejected under 35 U.S.C. §102(a) and/or §102(b) as being anticipated by Edwards *et al.* It is the Examiner's position that "treating ..... Type II diabetes mellitus" as recited in claim 1 is broad enough to encompass treating symptoms of the disease, such as painful neuropathy. It is submitted that it is possible to treat symptoms of a disease without treating the disease itself. As disclosed in Edwards *et al.* anti-convulsants, NSAIDs, opioids and anti-depressants have been widely used to treat patients with diabetes who suffer painful neuropathy. However, one could not conclude from this disclosure that claims drawn to a method of treating painful neuropathy associated with diabetes with an anti-convulsant, NSAID, opioid or anti-depressant are broad enough to encompass treating the underlying pathophysiology of diabetes *per se* such as the glucose and insulin dysregulation with an anti-convulsant, NSAID, opioid or anti-depressant. Although symptoms of a particular disease may disappear when treated with a drug it is generally held that the disease is being treated with the drug and not the symptoms of the disease. A physician is unlikely to prescribe an antibiotic to treat pain associated with a bacterial infection. The pain is symptomatic of and is caused by the underlying infection. The drug used to treat the infection does not treat the pain but rather the infection itself. Once the infection is treated the pain will go away. Therefore, it is not proper to conclude that claims drawn to the treatment of a disease are broad enough to include treatment of the symptoms since the symptoms are not being treated.

As disclosed in Edwards *et al.,* anti-convulsants such as gabapentin have been employed to treat painful diabetes neuropathy. To the best of applicants' knowledge, there is no record of any anti-convulsant being used to treat diabetes mellitus. None of the other drugs and classes of drugs referred to in Edwards *et al.*, *i.e*, NSAIDs, opioids and anti-depresssants, is known to be useful in treating diabetes *per se*. They are only

used to treat the symptom of pain associated with diabetic neuropathy. In fact, some of these drugs are also used to treat the pain associated with non-diabetic neuropathies such as post-herpetic neuralgia and other neuropathic pain syndromes. Given the disclosure in Edwards *et al.* one skilled in the art would not be led to use an anti-convulsant such as topiramate or any other anti-convulsant to treat or prevent the underlying pathophysiology of diabetes.

The Examiner has stated that, since Edwards *et al.* discloses that 26 patients ages 36 to 77 years were treated, "it is reasonable to conclude that at least some of the 26 patients had Type II or adult-onset diabetes". It is submitted that this conclusion is mere speculation on the part of the Examiner. Nowhere in Edwards *et al.* is there a reference to Type II diabetes. Edwards *et al.* does not identify the type of diabetes causing the painful neuropathy in the 26 patients treated. It is just as reasonable to conclude that all of the patients treated in Edwards *et al.* had Type I diabetes. Since neuropathy is defined as a disease abnormality of the nervous system, it is not associated solely with Type II diabetes.

In order to anticipate an invention under 35 U.S.C. §102(a) the invention must have been

".....known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, ..."

Applicants' invention relates to the use of anti-convulsant derivatives to treat or prevent the onset of Type II diabetes mellitus and Syndrome X. There is no mention in Edwards *et al.* of Type II diabetes or Syndrome X. There is nothing in Edwards *et al.* that would suggest that topiramate could be used to treat Type II diabetes or to prevent the onset of Type II diabetes. Edwards *et al.* stands for the proposition that topiramate can be used to treat the painful neuropathy associated with diabetes. Since Edwards *et al.* fails to indicate which type of diabetes caused the painful neuropathy being treated with topiramate, and since Edwards *et al.* fails to indicate that topiramate can be used to prevent the onset of Type II diabetes, and since Edwards *et al.* fails to even suggest that topiramate has any affect on the underlying disease itself, it is fair to conclude that Edwards *et al.* does not anticipate applicants' claimed invention.

In order to anticipate "a single reference must teach every limitation of the claimed invention". Mehl/Biophile International Corp V Milgram, 52 USPQ 2d, 1306 (Fed. Cir. 1999), cited by the Examiner. Since even an inherent teaching about treatment and/or prevention of Type II diabetes and Syndrome X is absent in the reference, it is submitted that Edwards *et al.* does not anticipate applicants' claimed invention.

The Examiner has stated that "even if none of the Edwards *et al.* patients had Type II diabetes ..... claims 1, 2, 15 and 16 are still anticipated because they read on prevention and do not require the patient to be suffering from any disease at all". Applicants take issue with this conclusion. The disclosure in Edwards *et al.* can hardly be deemed to anticipate applicants' claims to prevention since nowhere in the reference is

it even hinted that topiramate can be used to prevent the onset of diabetes. Edwards *et al.* stands only for the proposition that topiramate can be used to treat painful neuropathy associated with diabetes. Since the disclosure in Edwards *et al.* does not disclose a method of treating or preventing the onset of diabetes mellitus, it is submitted that applicants' claimed invention is not anticipated by the reference.

Reconsideration of the rejection of claims 1, 2, 10, 11, 15, 16, 20 and 21 under 35 U.S.C. §102(a) and/or §102(b) is courteously requested.

Claims 1-9 and 15-19 are again rejected under 35 U.S.C. §102(b) as being anticipated by Shank (U.S. patent No. 6,071,537). In order to anticipate an invention under 35 U.S.C. 102(b) the invention must have been

> "..... patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States,....."

The Examiner has stated that this rejection is made as to the preventive aspect of the claims; i.e. the mammalian recipient is not afflicted with Type II diabetes or Syndrome X.

Shank claims a method of treating obesity by the administration of an anti-convulsant compound. Applicants' invention claims a method of treating or preventing the development of Type II diabetes mellitus by the administration of an anti-convulsant derivative. Shank teaches the administration of compounds within the scope of the pending claims, including topiramate, to mammals suffering from obesity. The utility disclosed in Shank is a new use for these compounds. Method of treatment language is commonly employed to claim a new use for an old compound. The Examiner agrees that the reference does not mention Type II diabetes or Syndrome X but nevertheless concludes that applicants' claims are anticipated by the reference since "All that is needed is that" the reference teach the administration of a compound of the claims in amounts of the claims, to a mammal of the claims.

According to the Examiner "The steps of the method are old, and discovery of a new benefit for an old process does not render the old process patentable". In support of this conclusion the Examiner cites In re Woodruff. The claims in In re Woodruff were rejected under 35 U.S.C. §103 and not §102(b) as in the present case (see Conclusion on page 1937). The Woodruff application claimed a process for inhibiting the growth of fungi on refrigerated fresh fruits and vegetables while the McGill patent claimed a method of storing fresh leafy and head vegetables to maintain their fresh look. The only difference between the two processes was the amount of carbon monoxide employed. The court held that the Woodruff process was obvious over the disclosure in the McGill patent.

The Examiner states further that "merely because SHANK did not have one of Applicant's purposes in mind when the drug was administered does not alter the drug's physiological activity". The Examiner states further that "In the context of an

anticipation rejection, the Federal Circuit stated, 'Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." The Examiner cites Mehl/Biophile Int'l Corp. v. Milgraum in support of the rejection. This case described a patent infringement action involving a patent claiming a method for removing hair using a laser. The decision turned on whether the laser in contact with the skin would align it perpendicular to the skin surface and thereby substantially vertically over the follicle openings. In finding the Mehl/Biophile patent invalid the court held that the "natural result flowing from the operation as taught would result in "alignment of the laser light over a hair follicle as claimed in the application. Neither patent in the suit related to a method of treating a disease in mammals.

The Examiner states that "because SHANK deliberately intended the disclosed administration within the scope of the claims, and because the necessary result was prevention as claimed, the instant claims are anticipated regardless of whether or not SHANK appreciated that result". Applicants submit that the effect obtained in Shank is not prevention as stated by the Examiner since the administration of topiramate did not prevent the onset of obesity but rather caused a loss in body weight. (See column 3, line 61 to column 4, line 2.) Claim 1 of Shank claims a "method of treating obesity in a mammal comprising administering to said mammal a therapeutically effective amount of a compound" similar to those employed by applicants. Shank did not claim a method of preventing obesity in a mammal. It is difficult to see, therefore, how claims to a method of treating obesity can anticipate a claim to a method of preventing the onset of diabetes.

A process for removing hair follicles from the body can not be compared with a method of treating the human body systemically with a drug. Method of treatment claims are not typical process claims. As indicated above, a single reference must teach every limitation of the claimed invention. Applicants' claims are drawn to a method of preventing the onset of diabetes. Since Shank does not teach prevention of a disease but does teach a method of treating obesity which results in a loss of body weight, it is submitted that applicants' claimed method of preventing the onset of diabetes mellitus is not anticipated by the reference.

Reconsideration of the rejection of claims 1-9 and 15-19 under 35 U.S.C. §102(b) is courteously requested.

In view of the above discussion and the amendments herein being made to the claims, it is believed that all of the outstanding objections and rejections have been removed. Applicants respectfully request that a timely Notice of Allowance be issued in this application. In the event the Examiner adheres to the final rejection, entry of the amendment is requested so that the record on Appeal will be complete.

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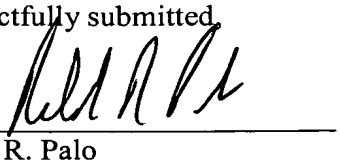
Respectfully submitted,



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